

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
THIS DOCUMENT RELATES TO ALL CASES	HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)

**CERTIFICATION OF ROSEMARIE RIDDELL BOGDAN IN OPPOSITION TO
DEFENDANTS' DAUBERT MOTION TO PRECLUDE OPINIONS OF PLAINTIFFS'
EXPERT DIPAK PANIGRAHY, M.D.**

Rosemarie Riddell Bogdan, hereby certifies as follows:

1. I am an attorney at law within the State of New York and a partner with the law firm of Martin, Harding & Mazzotti, LLP, and serve as Court-appointed Plaintiffs' Steering Committee Counsel. I am fully familiar with the facts and circumstances of these actions. I make this Certification in opposition to Defendants' motion to preclude opinions of the testimony of Dipak Panigrahy, M.D.
2. Attached hereto as **Exhibit A** is a true and accurate copy of Dr. Panigrahy's Expert Report and addendum served in MDL 2875.
3. Attached hereto as **Exhibit B** is a true and accurate copy of Dr. Panigrahy's CV served in MDL 2875.
4. Attached hereto as **Exhibit C** is a true and accurate copy of the complete transcript of the deposition of Dr. Dipak Panigrahy, in MDL 2875, dated September 9, 2021, September 10, 2021, and October 27, 2021.

5. Attached hereto as **Exhibit D** is a true and accurate copy of “*Control of Nitrosamine Impurities in Human Drugs; Guidance for Industry*” by the FDA Center for Drug Evaluation and Research (CDER), dated February 2021.

6. Attached hereto as **Exhibit E** is a true and accurate copy of “*ICH M7(R1) Guidance for Industry: Assessment & Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk*” dated March 2018.

7. Attached hereto as **Exhibit F** are true and accurate copies of excerpts of the deposition transcript of Dr. George Johnson, in MDL 2875 on October 4, 2021.

8. Attached hereto as **Exhibit G** are true and accurate copies of excerpts of the deposition transcript of Dr. Lewis Chodosh, in MDL 2875, on September 29, 2021.

9. Attached hereto as **Exhibit H** is a true and accurate copy of “*Lifetime exposure to rubber dusts, fumes and N-nitrosamines and cancer mortality in a cohort of British rubber workers with 49 years follow up*” by Hidajat et. al., dated 2019.

10. Attached hereto as **Exhibit I** is a true and accurate copy of an excerpt of Dr. Fryzek’s Expert Report served in MDL 2875.

11. Attached hereto as **Exhibit J** is a true and accurate copy of “*Interspecies scaling of the pharmacokinetics of N-nitrosodimethylamine*” by Gombar et. al., dated 1990; “*Pharmacokinetics of N-nitrosodimethylamine in swine*” by Gombar et. al., dated 1988; and “*Pharmacokinetics of N-nitrosodimethylamine in beagles*” by Gombar et. al., dated 1987.

12. Attached hereto as **Exhibit K** is a true and accurate copy of “*Effects on 4080 Rats of Chronic Ingestion of N-nitrosodiethylamine or N-nitrosodimethylamine: A Detailed Dose Response Study*” by Peto et. al., dated 1991.

13. Attached hereto as **Exhibit L** are true and accurate copies of excerpts of “*IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans: Some N-Nitroso Compounds*” Vol. 17, dated 1978.

14. Attached hereto as **Exhibit M** is a true and accurate copy of “FDA General Advice to ARB drug manufacturers”.

15. Attached hereto as **Exhibit N** is a true and accurate copy of “*WHO Concise International Chemical Assessment Document 38- N-Nitrosodimethylamine*” by Liteplo and Meek, dated 2002.

16. Attached hereto as **Exhibit O** is a true and accurate copy of ZHP recall notice for Valsartan; SOLCO00024226.

17. Attached hereto as **Exhibit P** are true and accurate copies of excerpts of the deposition transcript of Min Li, in MDL 2875 on April 22, 2021.

18. Attached hereto as **Exhibit Q** are true and accurate copies of excerpts of the deposition testimony of B.V. Ramarao, in MDL 2875 on April 29, 2021.

19. Attached hereto as **Exhibit R** is a true and accurate copy of ZHP’s test results to the FDA; SOLCO00028261.

20. Attached hereto as **Exhibit S** are true and accurate copies of excerpts of the deposition testimony of Hai Wang, in MDL 2875 on March 10, 2021.

21. Attached hereto as **Exhibit T** is a true and accurate copy of “*Dietary N-nitroso compounds and risk of pancreatic cancer; results from a large case-control study*” by Zheng et. al., dated 2018.

22. Attached hereto as **Exhibit U** is a true and accurate copy of Wasserstein et al. *The ASA Statement on p-Values: Context, Process, and Purpose*, The American Statistician (2016),70:2.

23. Attached hereto is a true and accurate copy of *In re Actos Pros. Liab. Litig.*, 2013 U.S. Dist. LEXIS 179235 (2013).

24. Attached hereto is a true and accurate copy of *Berman v. Mobil Shipping & Transp., Co.*, 2019 U.S. Dist. LEXIS 55671; 2019 WL 1510941 (2019) .

25. Attached hereto is a true and accurate copy of *Coffin v. AMETEK, Inc.*, 2020 U.S. Dist. LEXIS 169589; 2020 WL 5552113 (2020).

26. Attached hereto is a true and accurate copy of *McMunn v. Babcock & Wilcox Power Generation Group, Inc.*, 2013 US Dist. LEXIS 100259; WL 3487560 (2013).

27. Attached hereto is a true and accurate copy of *Gorton v. Air & Liquid Sys. Cor.*, 2020 U.S. Dist. LEXIS 129606; 2020 WL 4193649, (M.D. Pa. 2020).

28. Attached hereto is a true and accurate copy of *Hoffeditz v. AM Gen, LLC*, 2017 U.S. Dist. LEXIS 123493; 2017 WL 3332263 (D.N.J., 2017).

MARTIN, HARDING & MAZZOTTI LLP
Attorneys for Plaintiffs

By: /s/ Rosemarie Riddell Bogdan

Dated: December 1, 2021

CERTIFICATE OF SERVICE

I hereby certify that on December 1, 2021, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notifications of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ Rosemarie Riddell Bogdan

Rosemarie Riddell Bogdan